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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,597	08/16/2001	Jozef Reinier Cornelis Jansen	DVME-1015US	4150
21302	7590	06/08/2004	EXAMINER	
KNOBLE, YOSHIDA & DUNLEAVY EIGHT PENN CENTER SUITE 1350, 1628 JOHN F KENNEDY BLVD PHILADELPHIA, PA 19103			BOCKELMAN, MARK	
			ART UNIT	PAPER NUMBER
			3762	3

DATE MAILED: 06/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/913,597

Applicant(s)

JANSEN ET AL.

Examiner

Mark W Bockelman

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 2.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Specification***

The examiner notes that applicant references NL-B-1 005572 on page 2 of applicant's specification. The examiner requests that applicant provide a translated copy of the document for consideration in future office actions.

As the result of improper amendment format used by applicant in the international stage of this application, applicant's amended sheets 6, 7, 9, 10 and 11 submitted to the IB have NOT been entered and the following office action is based upon the PCT application as originally filed.

The disclosure is objected to because of the following informalities: On page 6 of the specification the applicant has "6=4 to 6=12". It is believed applicant meant "6" to be a "t". In addition applicant refers to areas such as "A" which is not identified in the figures, only a point a. Applicant should amend the specification to point out that the area "A" is the area defined by the points a,b,c,d if that is applicant's intention.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3762

Regarding claims 1, 2, 5 and 6, the term "preferably" renders the claim indefinite because it is unclear whether the limitation(s) following the term is part of the claimed invention. See MPEP § 2173.05(d). In other words, the claim language is unclear as to whether the claim scope is limited to the narrower "preferably" clause or whether the step following the term would be better served in a dependent claim that would further limit the scope of its independent claim.

Dependent claims 3-4, 7 fail to clarify the indefiniteness of claims 1 and 5 and thus are rejected as well under 112 second paragraph.

In addition, the examiner agrees with the international searcher's opinion that claims 1 and 5 are confusing since applicant is claiming that a first variation in a indicator value is measured prior to injection of the indicator and thus the claim is considered confusing when in the art indicators are sometime dyes and the like.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman USPN 5,797,398 in view of Jansen et al. USPN 4,595,015.

Art Unit: 3762

Bowman teaches the use of a catheter with sensors and a coil member 21 for heating blood passing through the heart so as to determine the cardiac output of the heart. The heat is applied to the blood for at least a period of one respiratory cycle and the change in heat in the blood serves as an "indicator value" in the blood stream. Sensors 19 and 20 measure temperature with sensor 20 measuring the temperature down stream of the heater application site. The patients respiration cycle and the variation in temperature due to each respiration cycle along with an average for many respiration cycles is determine as shown in process I, figure 3. The amount of heat applied to the blood is "established" and predetermined and used to determine the cardiac output (column 2 lines 47-67) along with the measured change in the heat measured at the second sensor. Cardiac output is determined based upon the difference in the change in average temperature with the heat applied (a.k.a. phase (on)) and the average temperature with the heater off (a.k.a.) with the latter determined just prior to the former. (see figure 4). Since Bowman teaches that the two average temperatures are measured over at least one respiratory cycle the computation of cardiac output would be the average indicator value change in temperature for one cycle minus the average change in the first variation (i.e. phase off) times  $n$  where  $n = 1$ .

With respect to claim 2, the examiner considers interprets the Bowman disclosure to include a second variation, that is a second temperature measurement of a second respiratory cycle (when two cycles for determining

Art Unit: 3762

phase (off) which first temperature and second temperature variations are averaged and used in the Bowman computation for multiple cycle sampling.

Applicant differs from Bowman in that Bowman uses a heating device that heats the blood rather than using the conventional injection of cooled (or heated) fluid which would have been an obvious substitution with Jansen et al cited as one of many conventional thermal dilution systems.

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bowman USPN 5,797,198 in view of Jansen et al and further in view of Nikolic et al. The examiner refers applicant to the previous applied rejection for association of elements with Bowman and Jansen et al. Claim 5 adds two additional elements as compared to claim 1, namely a controller for injecting fluid, which is apparent in the conventional Jansen device and a second sensor for determining the respiratory cycle. While Bowman teaches the determination of the respiratory cycle he does not state specifically how he does so. It is believed that either a peak detector or separate sensor would be employed. The examiner would consider it obvious to include an additional sensor such as a blood pressure sensor as used in Nikolic et al (see figure 4 and associated text) for determining the respiratory cycle for the further computations of temperature variation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W Bockelman whose telephone number

Art Unit: 3762


is (703)-308-2112. The examiner can normally be reached on Monday - Thursday 10-8:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

June 6, 2004

  
MARK BOCKELMAN  
PRIMARY EXAMINER